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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/905,709 08/05/97 STERN D 52876/JPW/JM

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HM12/0629

EXAMINER

LAZAR WESLEY, E

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/905,709

Applicant(s)

Stern

Examiner
Eliane Lazar-Wesley

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 11, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13, 15-27, 29, 30, and 32-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, 15-27, 29, 30, and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20 20) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on May 11, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/905,709 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-10, 12, 13, 15-27, 29, 30, 32-35 are under consideration.

Oath

2. The new oath has been received.

Priority

3. Applicant's claim for priority under 35 U.S.C. 120 is acknowledged. However, the applications 08/592, 070, filed January 26, 1996, and 08/755,235, filed November 22, 1996, upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the claims of this application. Applications 08/592,070 and 08/755,235 do not support claims to methods to prevent accelerated development of atherosclerosis, or to inhibit progression of a macrovessel disease, which comprise administering the V-domain of sRAGE.

Applicants has not specified how the parent cases are related to the instant application, i.e. if they are a continuation-in-part.

The priority date for this application remains August 05, 1997, which is the filing date of application 08/905,709.

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IDS

The Information Disclosure Statement (PTO 1449) has been received. As indicated on the IDS signed by the Examiner, some references have not been considered as they have not been provided by Applicants.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-10, 12, 13, 15-27, 29, 30, 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Morser, US Patent 5,864,018.

The claims are to methods which comprise administering apolypeptide comprising the V-domain of sRAGE or a derivative thereof capable of inhibiibg the interaction of AGE and RAGE.

Morser teaches peptides like the peptide of SEQ ID No:8, which block the interaction of AGE and sRAGE (col.6, lines 41-52 and col.7, lines 13-20). While Morser defines these peptides by their sequence, these peptides constitute in fact fragments of sRAGE of about 10 amino acids in length, located in the V domain of SRAGE (see attached). The peptides of Morser are derivatives of the V-domain of SRAGE, as the specification, at page 8, line 30+, recites that : "The polypeptide

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may be a derivative of soluble receptor for advanced glycation end products (sRAGE). The polypeptide may be a soluble extracellular *portion of a receptor* for advanced glycation end product...". He teaches that the soluble peptides of the invention will comprise one or more of the Ig-like domains of the extracellular region of RAGE (col.5, lines 24-28), therefore the soluble extracellular domain (sRAGE), comprising one Ig V and two IgC domains, is envisioned. He teaches that these polypeptides are useful in treating or preventing disorders which result from excessive levels of AGEs (col.19, lines 1-24), in particular in diabetic microvasculopathy, occlusive vascular disorders and atherosclerosis. He teaches therapeutically effective amounts of the polypeptides, and methods of administration (col.19, line 48 continuing through col.20). Claims 1-4, 8, 10, 13, 15-21, 25, 27, 30, 32-35 are anticipated. Claims 5-7, 9, 22-24, 26 are included in the rejections, as the methods apply to disorders that are associated with diabetes or macrovessel diseases. Claims 12 and 29 are included in the rejection, as the polypeptides of Moser encompass a 10 kilodalton domain of sRAGE.

Please note that the peptides of SEQ ID No:18, 12, 13 and 5 are also fragments of sRAGE of about 10 amino acids in length, located in the V domain of SRAGE (see attached), able to block the interaction of AGE and sRAGE.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

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Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

June 27, 2001

ELW


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600